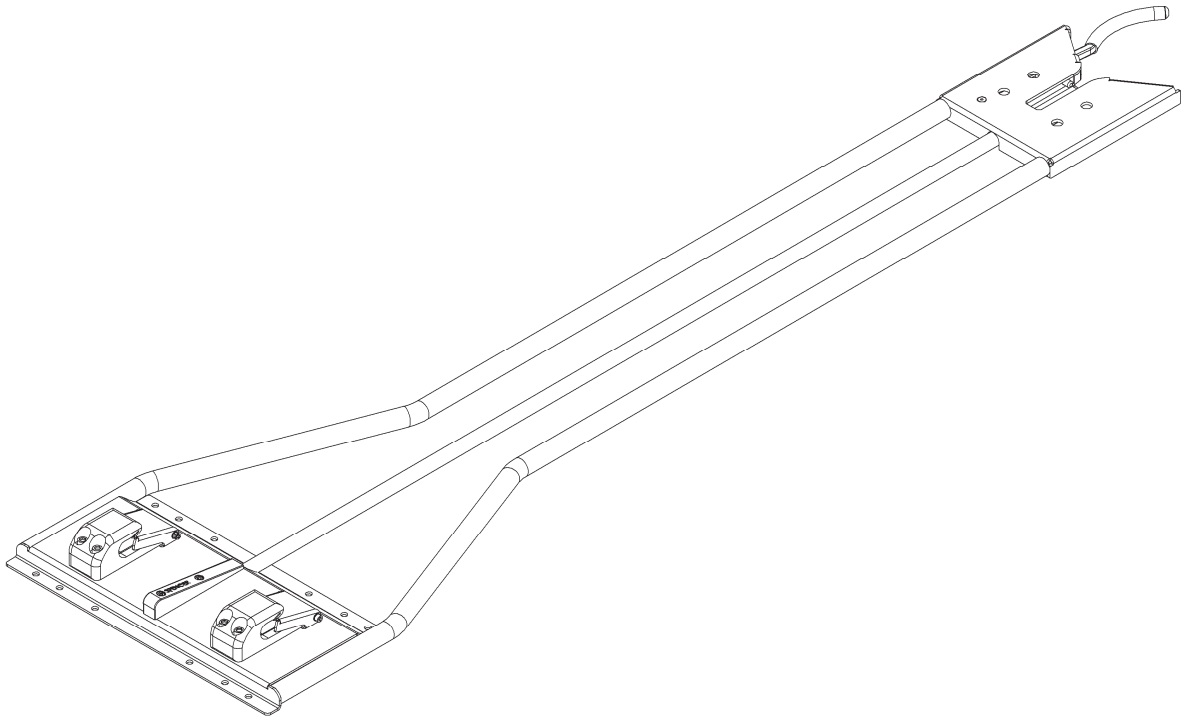
User's Manual

R-Max
10 G fixing system for stretchers



CE This appliance conforms with the directive 93/42/CEE "Medical Devices".

Guarantee of Quality system for the production and the final control of the products certified by the notifying body TÜV SÜD Product Service GmbH.

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Spencer Italia S.r.l. • Strada Cavi,7 • 43044 Collecchio (PR) ITALY
Tel. +39 0521.541111 • Fax +39 0521.541222 • E-mail: info@spencer.it

Thank you for choosing a Spencer product

1. GENERAL INFORMATION

1.1 Aim and contents

The aim of this manual is to supply all the information necessary so that the client, will not only attain adequate use of the appliance, he will also be capable of using the instrument in the most autonomous and secure way possible. This includes information regarding technical aspects, functioning, maintenance, spare parts and safety.

1.2 Conservation of the instruction manual

The instruction and maintenance manual must be kept together with the product, for the whole life of the device, inside the specially provided container and above all, away from any substances or liquids which could compromise perfect legibility.

1.3 Symbols used

Symbol	Meaning
	General or specific warning
	See instructions for use
LOT	Lot number
REF	Product code
CE	The product is compliant with the specifications of the Directive 93/42/CEE

1.4 Servicing requests

For any information regarding the use, maintenance and installation, please contact the Spencer Customer Care Service on tel. 0039 0521 541111, fax 0039 0521 541222, e-mail info@spencer.it or write to Spencer Italia S.r.l. - Strada Cavi, 7 - 43044 Collecchio (Parma) - ITALY. In order to facilitate the assistance service, please always indicate or communicate the serial number (SN) or lot number (LOT) shown on the label applied on the box or on the device.

1.5 Demolition

When the devices are no more suitable for being used, if they haven't been contaminated by any particular agents, they can be disposed of as normal solid waste, otherwise follow the current regulations about demolition.

1.6 Labelling

Each device has got an identifying label, positioned on the device itself and/or on the box. This label includes information about the Manufacturer, the product, CE mark, lot number (LOT). It must never be removed or covered.

2. WARNINGS

2.1 General warnings

- The product must be used by trained personnel only, having attended specific training for this device and not for similar products.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- Spencer Italia S.r.l. is always at your disposal to plan trainings on products.
- Before carrying out any kind of operation on the appliance (training, installation, use), the operator must carefully read the enclosed instructions, paying particular attention to the correct safety precautions and to the procedures to be followed for installation and for correct use.
- If the instructions belong to another device and not the device received, inform the Manufacturer immediately and avoid use of the device.
- In the case of any doubts as to the correct interpretation of the instructions, please contact Spencer Italia S.r.l. for any necessary clarifications.
- Do not allow untrained persons to help during the use of the device, because they could cause damage to the patient or to themselves.
- Regularly check the appliance, carry out the prescribed maintenance and respect the average life span, as indicated by the Manufacturer in this User's Manual.
- Before each use of device the perfect operating state of the device must be checked as specified in the Instruction manual. If any damage or abnormalities which could in any way influence the correct functioning and the safety of the device, of the patient and or of the user are detected, the device must be immediately removed from service and the Manufacturer must be contacted.

- If any failure or incorrect functioning of the device is detected, it must be immediately substituted with a similar item so that the rescue procedures are guaranteed without any interruption.
- Use of the device in anyway other than described in this manual is forbidden.
- Do not alter or modify in any way the appliance; any such interference could cause malfunctions and injury to the patient and/or rescuer.
- The appliance must not in any way be tampered with (modification, adjustment, addition, replacement). In such cases all responsibility will be denied for any malfunctions or injuries caused by the appliance itself; moreover CE certification and product warranty will be considered void.
- Those who modify or have modified, prepare or have prepared medical appliances in such a way that they no longer serve the purpose for which they were intended, or no longer supply the intended service, must satisfy the valid conditions for the introduction onto the market.
- Handle with care.
- Ensure that all the necessary precautions are taken in order to avoid the hazards that can arise as the result of contact with blood or body fluids.
- Register and store with these instructions: lot number, place and date of purchase, first date of use, date of checks, name of users, any comments.
- When the device is being used, the assistance of qualified staff must be guaranteed.
- Do not store the device underneath any heavy objects which could cause structural damage.
- Store in a cool, dry, dark place and do not expose to direct sun.
- Store and transport device in its original packaging.
- The device not be exposed to or come into contact with any source of combustion or inflammable agents.
- Position and adjust the device taking care not to cause any obstruction to rescuers and or any other rescue equipment.
- Attention: laboratory testing, post production tests, instruction manuals cannot always consider every possible scenario for use. This means that in some cases the performance of the product could be notable different from results to date obtained. Instructions are continually being updated and are under tight surveillance of fully qualified staffs with adequate technical formation.
- With reference to the D. Lgs. 24th February 1997, n. 46 emended by D. Lgs. 25/01/2010, n. 37 – Acknowledgement of Directive 93/42/CEE and 2007/47/CE, we remind both public and private operators that they are obliged to report any accident that involves any medical device to the Ministry of Health and to the Manufacture as specified and within time given by the European regulations.
  In addition, both public and private operators are obliged to inform the Manufacturer of any measures that should be adopted to make the steps necessary to guarantee the safety and the health of the patients and the users of any medical device.

2.2 Specific warnings

- Establish a maintenance program and periodic testing, identifying an reference employee. The person to whom the ordinary maintenance of the device is entrusted must ensure the basic requirements foreseen by the Manufacturer in the user's manual.
- Training routines must be registered on a special register in which the names of those trained, of the trainers, date and place are indicated. This register which will certify the eligibility of the operators to use the Spencer device has to be kept for a period of 10 years after the disposal of the device itself. This register will be made available to the Competent Authorities and/or Manufacturer if requested.
- Use only accessories/spare parts that are original or approved by Spencer Italia S.r.l., in order to carry out any operation without causing any alteration or modification to the device, otherwise we assume no responsibility for the proper functioning or damage resulting from device to the patient or the operator and warranty and will be considered void according to the compliance to the Medical Device Directive 93/42/CEE.
- Never leave the patient unassisted on the device, because he may be injured.
- The device, after washing, should be allowed to dry completely before storing, away from sunlight and direct heating sources.
- The lubrication should be done after cleaning and complete drying.
- Follow the procedures approved by the Emergency Medical Services for the immobilization and transport of the patient.
- Follow the procedures approved by the Emergency Medical Services for the placement and transport of the patient.
- Avoid contact with sharp objects.
- Do not use if the device is excessively worn.
- Avoid pulling the device on rough surfaces.
- Condensation, water, ice and accumulations of dust can affect the correct functioning of the device.

2.3 Contraindications and side effects

The use of this device, if used as described in this manual, does not present any contraindications or collateral effects.

3. DESCRIPTION OF PRODUCT

3.1 Intended use

Spencer R-Max is a fastening system that allows the complete stability of the transport device on the ambulance floor, especially designed through three points in for the stretcher's fixation.

3.2 Main components

n°	Description of component	Material
1	Command handle	Steel
2	Back plates	Steel
3	Frame	Steel
4	Front plates	Steel
5	Locking front latch rod	Aluminium
6	Fastening tab	Steel

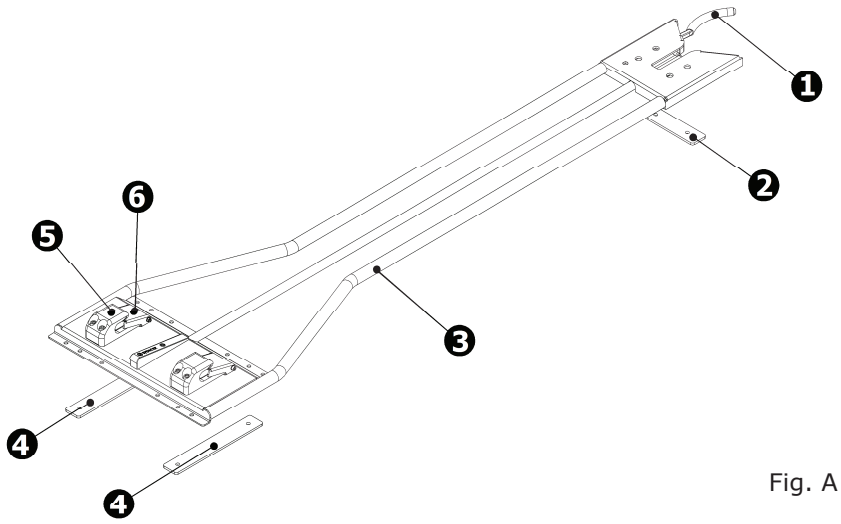

Fig. A

3.3 Models

These basic models could be modified, with reference to codes and/or descriptions without any previous notification.

ST42702C R-Max certified 10 G fixing system for stretchers

3.4 Technical data

Characteristics	
Width (mm)	1800
Length (mm)	445
Height (mm)	75
Weight (kg)	9

3.5 Reference standards

Reference	Title of document
MDD 93/42/CEE	European Directive about Medical Devices
MDD 2007/47/CEE	Modifications to 90/385/CEE Directive about active implants, Directive 93/42/CEE about medical devices and Directive 98/8/CE about the introduction of biocides onto the market
Legislative Decree 24/02/1997, n. 46	Application of the 93/42/CEE Directive about Medical Devices
Legislative Decree 25/01/2010, n. 35	Modifications and additions to the 20/02/97 Decree n. 46
UNI EN ISO 9001	Managing systems for quality: requirements
UNI EN ISO 9000	Managing systems for quality: basis and vocabulary
UNI EN ISO 13485	Medical Devices - Managing systems for quality – Requirements for regulamentation requirements
UNI EN 1865-1	Specification for stretchers and other equipment for patient's transport on ambulances
UNI EN 1789	Medical vehicles and their equipment - Ambulances
UNI EN ISO 14971	Application of risks managing to medical devices
UNI CEI EN 980	Graphic symbols used for medical devices labelling
UNI CEI EN 1041	Information supplied by the medical devices manufacturer
CEI EN 62366	Medical Devices - Application of the utilisation characteristics of engineering to medical devices
MEDDEV 2.4/1a-b	Guideline for the classification of medical devices
NB-MED 2.5.1 /Rec 5	Technical Documentation
MEDDEV 2.7.1	Clinical Data
MEDDEV 2.12/1	Medical Devices vigilance system

UNI EN 14155	Clinical evaluation of the medical devices for human beings - Part 2: Clinical evaluation plans
BS OHSAS 18001	Managing systems for safety and health at workplace

3.6 Environmental conditions

Functioning temperature: from -20 to +60 °C
Storage temperature: from -20 to +60 °C
Relative humidity: from 5 to 85%

4. OPERATING INSTRUCTIONS

4.1 Transport and storage

Before transporting the appliance, make sure that it is correctly packaged ensuring also that there are no risks of shocks, bumps or falls during the transport itself.
Keep the original packaging for use in case of any further transport and for storage. Damage to the appliance caused during transport and handling is not covered by the guarantee. Repairs or replacement of the damaged parts are the responsibility of the client. The device must be stored in a dry, cool area away from direct sunlight. It must not be placed in contact with any substances or chemical agents which could cause damage and reduce safety characteristics.

4.2 Preparation

On receipt of the product:

- Remove the packaging and display the material so that all components are visible.
- Check that all the components/pieces on the accompanying list are present.

The appliance must be checked before every use so as to reveal any working abnormalities and/or damage caused by transport and/or storage. In particular, check:

- General functionality of the device
- Cleanliness of the device
- Absence of cuts, holes, tears on the structure
- Proper tightening of the screws and bolts
- Status of wear (moving parts)
- Integrity of components
- Lubrication of moving parts
- Burst of spring
- The welds are intact, no cracks or breaks
- No piping or metal foil has kinks or cracks

If the above conditions are met, the device may be considered ready for use, otherwise you must immediately remove the device from service and contact the Manufacturer.

4.3 Requirements of the emergency vehicle

Spencer R-Max has been designed for installation on the ambulance. The vehicle should have the following characteristics:

- level tread surface
- tead surface long and large enough to freely house the fixing system piano
- to ensure proper use of the fixation system, you should install it on an emergency vehicle meets the requirements specified in EN 1789, otherwise the manufacturer can not be held responsible for any failures or anomalies generated by the use of an unsuitable surface.

4.4 Functioning

4.4.1 Fixing the hook to the ambulance platform

1. Position the hook on the ambulance platform in the point where it will be fixed.
2. Through the holes in the hook, mark the position for the holes. Two back holes and four front holes must be made.
3. Position the plates under the ambulance platform so that the holes correspond with those already made.
4. Using TCEI M8 screws (not included), washers Ø 8 and automatic blocking nuts M8 (fig. B) fix all parts together. There are many different possibilities for choosing the holes in order to facilitate the fixing operations.

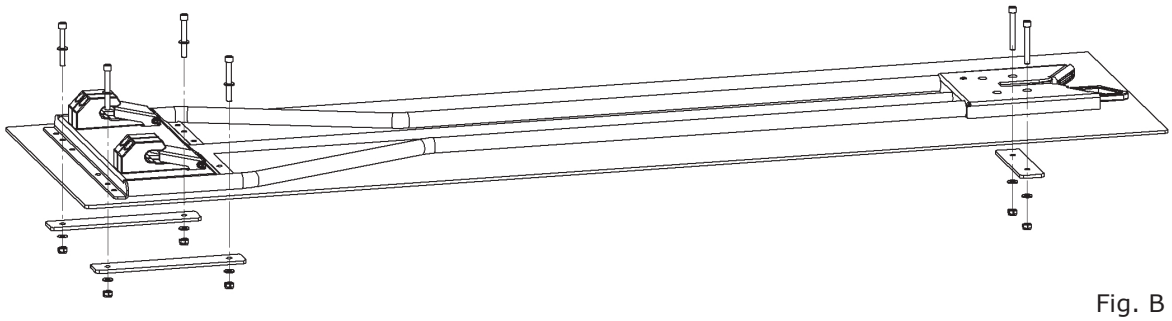

Fig. B

4.4.2 Fixing the stretcher to the R-Max

1. Load the transport device into the ambulance following the standard procedure.
2. The FA (n° 7 fig. C) rod of the stretcher will run over the hook until it attaches at the front to the fixing blocks (n° 5 fig C), which will hold with their hooks (n° 6 fig. C), which will close as the rod passes.
3. The thrust block (n° 8 fig. D), which is at the back of the stretcher follows the path of the the hook guides which will guide it to the mouth of the dovetail plate (n° 9 fig. D), blocking it by the small piston (n° 10 fig. D).

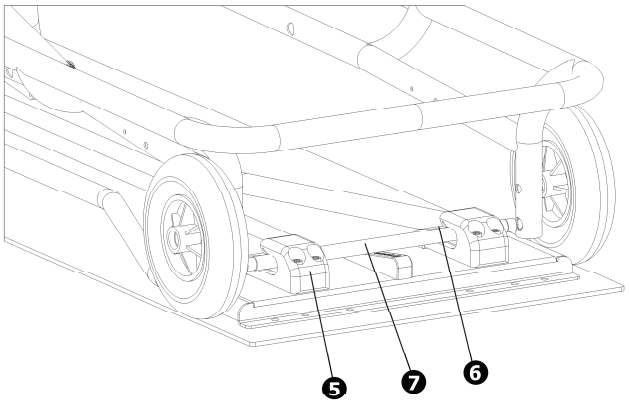

Fig. C

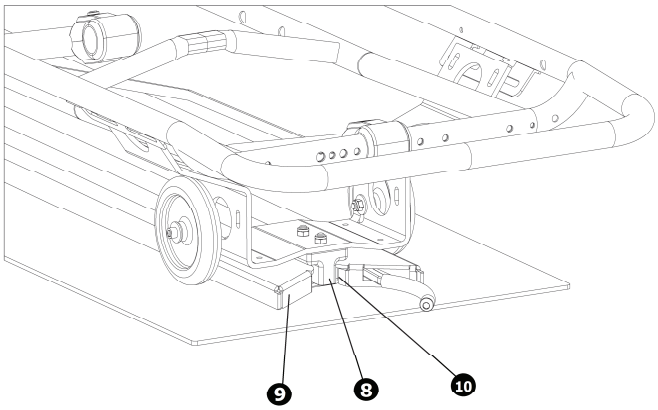

Fig. D

4.4.3 Unlocking the stretcher from the R-Max

1. To unblock the device from the 10 G hook, pull the handle comand (n° 1 fig. E) towards the operator as far as it will go and this will permit the hook and the piston to open.
2. With the other hand, grasp the frame (n° 11 fig. E) of the stretcher and pull it towards the operator so that the thrust block and FA rod will disengage from their seat.

The two operators should be performed at the same time.

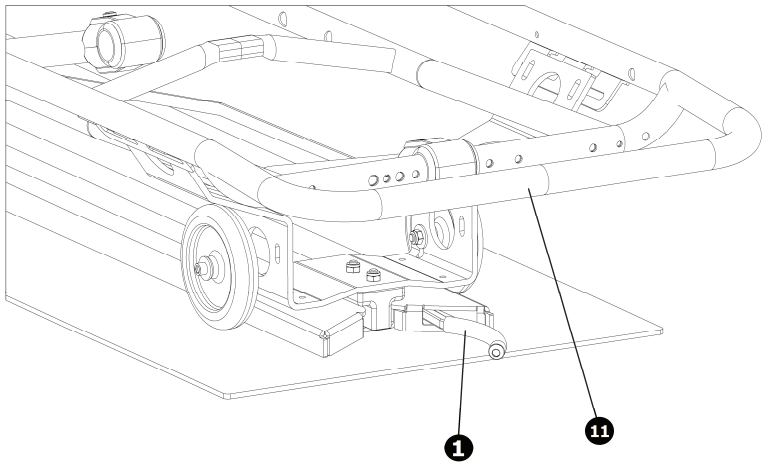

Fig. E

4.5 Troubleshooting

PROBLEM	CAUSE	REMEDY
The piston and the hook do not open up	The handle command has not been activated	Press button as far as possible
	The stainless steel movement rod has been cut	Immediately put the device out of service and contact the Service Centre
Damages to the structure	Incorrect use or not adequately trained staff	Immediately put the device out of service and contact the Service Centre

5. MAINTENANCE AND CLEANING

5.1 Cleaning

Failure to carry out the correct cleaning routine could increase the risk of cross infection.

The operator must always wear adequate personal protection such as gloves and mask etc. during all checking and cleaning procedures.

The metal parts that are exposed to external agents usually undergo treatment and/or coating to better their resistance.
Exposed parts should be cleaned with a sponge soaked in a delicate detergent and dry with a soft duster or chammy leather. For a shiny appearance we recommend the use of detergents or waxes used by car builders. We recommend the use Spencer STX 99 polish (code ST50000E) on the metal parts.
Rinse thoroughly with warm water making sure that you have removed all traces of detergent, which may deteriorate or compromise the integrity and durability of the device.
High pressure water cleaning systems should not be used; water could penetrate in the junctions and eliminate the grease which would increase the risk of corrosion.
Drying after washing or after use in wet environments must be natural and not forced, do not use flames or other sources of direct heat.

5.2 Maintenance

5.2.1 Precautionary maintenance

The person who carries out the precautionary maintenance of the appliance (user in person, Manufacturer/supplier or a third party) has to guarantee the following basic requirements:

- Technical knowledge of the appliance and of the periodic maintenance procedures as described in these instructions.
- Specific qualifications and training in the maintenance operations of the appliance in question.
- The use of components/replacement parts/accessories that are either original or approved by the supplier, in such a way that each operation causes no alteration or modification to the appliance.
- Possession of the checklist of operations carried out on the appliance.
- Guarantee complete adherence to the instructions of the Directive 93/42/CEE which includes also the obligation towards the Manufacturer to maintain post sales records and traceability of the appliance if requested.

During all checking, maintenance and cleaning procedures, the operator must wear adequate personal protection such as gloves, mask, glasses etc.

Checks to be carried out before and after each use, and at least every **3** months, are as follows:

- General functionality of the device
- Cleanliness of the device
- Absence of cuts, holes, tears on the structure
- Proper tightening of the screws and bolts

- Status of wear (moving parts)
- Integrity of components
- Lubrication of moving parts
- Burst of spring
- The welds are intact, no cracks or breaks
- No piping or metal foil has kinks or cracks

The person responsible for routine maintenance can identify damaged/worn parts, but the replacement or restoration of the them can only be done by the manufacturer or or by an authorized service center.

The inspection frequency is determined by factors such as legal requirements, the type of use, frequency of use, environmental conditions during use and storage. Please note that you must do the cleaning as described in paragraph 5.1 and verify functionality before and after each use. Spencer Italia S.r.l. declines any responsibility for the proper functioning or damages caused to the patient or user by the use of devices not subject to routine maintenance, warranty and will void the compliance to the Medical Device Directive 93/42/CEE.

5.2.2 Periodic maintenance

The device must be serviced by the manufacturer or by an authorised centre every year.

If the correct revision is not carried out, the CE branding will no longer be considered valid as it will no longer be compliant with the 93/42/CE Directive for Medical Devices and therefore there is the possibility that it is no longer compliant with the safety standards declared by the Manufacturer at time of purchase.

Spencer Italia S.r.l. will take no responsibility the incorrect functioning or any damage caused by a device that has not undergone regular revision.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

5.2.3 Special servicing

Only the Manufacturer or centres with written authorisation are authorised to complete any special servicing operations.

For any operations that are not carried out directly by the Manufacturer but by an authorised centre, we have to underline that a report regarding all operations carried out must be requested. This will permit both Spencer Italia S.r.l. and the end user to keep a log book regarding the operations carried out on the device.

The device, if used as indicated in the following instruction manual, has an average life span of **5** years. The life span can be expanded only following a general revision of the product that must be carried out by the Manufacturer or by a centre authorised by the Manufacturer.

Spencer Italia S.r.l. will accept no responsibility for the incorrect functioning and/or damage caused by the use of any device which has not been repaired, or certified on expiry date by the Manufacturer or by one of the Manufacturer's Authorised Service centres. Warranty will be considered void in compliance with the Medical Device Directive 93/42/EEC.

6. ACCESSORIES AND SPARE PARTS

There aren’t any accessories or spare parts for this device.

ATTACHMENT A – TRAINING REGISTER

The product must be used by trained personnel only, having attended specific training for this device and not for similar products.

Keep this document at least 10 years from the end of life of the device.

Operator's name	Training date		Training method (user's manual, during service, former class, etc.)	Trainer
	Basic training	Advanced training		

ATTACHMENT B – MAINTENANCE REGISTER

Keep this document at least 10 years from the end of life of the device.

Perform the required maintenance and to respect the life span of the device, as indicated by the Manufacturer in the User's Manual.

Code and description of the device	
Purchase date	
Lot (LOT) or serial number (SN)	
Bought by	

SERVICE DATE	KIND OF SERVICE (Maintenance/ check/ extension of life span)	OPERATIONS MADE ON THE DEVICE	RESULT	PERSON IN CHARGE OF SERVICE (Operator/ Authorized centre/ Manufacturer)

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